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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,143	12/21/2001	John S. Bobo	108774	5486

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EXAMINER	
VENKAT, JYOTHSNA A	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,143	BOBO ET AL.	
	Examiner	Art Unit	
	JYOTHSNA A VENKAT Ph. D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-149* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 (part), 3(part), 4-7, and 23 (part) drawn to a composition comprising a chemical structure were in **R'X is an amino acid residue**, classified in classes 536, 554-544, subclass 1+ depending on the nature of the amino acid and substituent R.

II. Claims 1-2(part), 3(part), (8 (part) and 9-12, 23(part) drawn to a composition comprising chemical moiety wherein R'X **is a payload which a therapeutic agent**, classified in class 514, subclass 1+ depending on the nature of the therapeutic agent.

III. Claims 1-2(part), 3(part), and 13-16, 23(part) drawn to a composition comprising chemical moiety wherein structure **R'X is a payload which an imaging agent,** classified in class 514, subclass 1+ depending on the nature of the imaging agent.

IV. Claims 1-2(part), 3(part), and 17-22, 23(part) drawn to a composition comprising a chemical moiety wherein structure **R'X is a payload which is a targeting moiety** classified in class 514, subclass 1+ depending on the nature of the imaging agent.

V. Claims 24-27 (part), and 30-31 drawn to a composition comprising a polymer **comprising at least five or more subunits where in R''X is amino acid**

residue, classified in classes 524-528, subclasses 1+ depending on the nature of the polymer and amino acid.

VI. Claims 24-27 (part) 32(part), 35-36, and 47-48(part) drawn to a composition comprising a **polymer comprising at least five or more subunits a where in R'X is a payload which is a therapeutic agent.**

VII. Claims 24-27 (part), 32(part), 37-40 and 47-48 (part) drawn to a composition comprising a **polymer comprising at least five or more subunits a where in R'X is a payload, which is an imaging agent.**

VIII. Claims 24-27 (part), 32 (part), 41-46 and 47-48 (part) drawn to a composition comprising a **polymer comprising at least five or more subunits a where in R'X is a payload, which is a targeting moiety.**

IX. Claims 24-27 (part), and 28-29(part) drawn to a composition comprising a **polymer comprising at least five or more subunits and further comprising a second polymer** where in **R''X is amino acid residue,**

X. Claims 24-27 (part), and 28-29(part), drawn to a composition comprising **a polymer comprising at least five or more subunits and further comprising a second polymer** where in **R'X is a payload which is a therapeutic agent.**

XI. Claims 24-27 (part), and 28-29(part) drawn to a composition comprising a **polymer comprising at least five or more subunits and further comprising a second polymer** where in **R'X is a payload which is an imaging agent.**

XII. Claims 24-27 (part), and 28-29 (part) drawn to a composition comprising a **polymer comprising at least five or more subunits and further comprising a second polymer** where in **R'X is a payload which is a targeting moiety.**

XIII. Claims 49-50(part) and 51-52, 68(part) drawn to a biocompatible **polymer formed by polymerization of monomers where in R'X is an amino acid residue**

XIV Claims 49-50(part), 53(part) and 54-57, 68 (part) drawn to a biocompatible **polymer formed by polymerization of monomers where in R'X is a payload, which is a therapeutic agent.**

XV Claims 49-50(part), 53(part) and 58-61, 68(part) drawn to a biocompatible **polymer formed by polymerization of monomers where in R'X is a payload, which is an imaging agent.**

XVI. Claims 49-50(part), 53(part) and 62-67, 68(part) drawn to a biocompatible **polymer formed by polymerization of monomers where in R'X is a payload, which is a targeting moiety.**

XVII. Claims 69-71 (part) drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the said composition with a substance capable of initiating polymerization** of said monomer to form the biocompatible polymer **where in R'X is an amino acid residue**

XVIII. Claims 69-71 (part) drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the**

said composition with a substance capable of initiating polymerization of said monomer to form the biocompatible polymer **where in R'X is a payload which is a therapeutic agent.**

XI. Claims 69-71 (part) drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the said composition with a substance capable of initiating polymerization** of said monomer to form the biocompatible polymer **where in R'X is a payload which is an imaging agent.**

XX. Claims 69-71 (part) drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the said composition with a substance capable of initiating polymerization** of said monomer to form the biocompatible polymer **where in R'X is a payload which is a targeting moiety.**

XI. Claims 69-71 (part), 73-81(part) and 87 drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the said composition with a biological tissue of a patient in vivo where in R'X is an amino acid residue.**

XII. Claims 69-71 (part), 73-83(part), 84-86, 88 (part), and 89-97 drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the said composition with a biological tissue of a patient in vivo where in payload which is a therapeutic agent**

XIII. Claims 69-71 (part), 73-83(part), 88 (part), and 98-103, drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the said composition with a biological tissue of a patient in vivo where in R'X is a payload which is an imaging agent**

XIV. Claims 69-71 (part), 73-83(part), 88 (part) and 104-108 drawn to a **method of forming a biocompatible polymer,** comprising providing a monomer comprising the structure **and contacting the said composition with a biological tissue of a patient in vivo where in R'X is a payload which is a targeting moiety.**

XV. Claims 109-121 (part), and 127 drawn to a **method for delivering a therapeutic or diagnostic agent where in R'X is an amino acid residue.**

XVI. Claims 109-121 (part), 122-123(part), 124-126, 128(part), and 130-138 drawn to a **method for delivering a therapeutic or diagnostic agent where in R'X is a payload which is a therapeutic agent.**

XVII. Claims 109-121 (part), 122-123(part), 128(part) and 138-143 drawn to a **method for delivering a therapeutic or diagnostic agent where in R'X is a pay load which is an imaging agent.**

XVIII. Claims 109-121 (part), 12-123(part), 128 (part), and 144-148 drawn to a **method for delivering a therapeutic or diagnostic agent where in R'X is a payload which is a targeting moiety.**

XIX. Claim 149 (part), drawn to an **in vitro system for growth of cells where in R'X is an amino acid residue.**

XXX. Claim 149 (part), drawn to an **in vitro system for growth of cells where in R'X is a payload, which is a therapeutic agent.**

XXXI. Claim 149 (part), drawn to an **in vitro system for growth of cells where in R'X is a payload, which is an imaging agent.**

XXXII. Claim 149 (part) drawn to an **in vitro system for growth of cells where in R'X is a payload, which is a targeting moiety.**

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group I is drawn to composition, which has an amino acid, which is distinct and separate from group II that has a therapeutic agent. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group I would not anticipate or render obvious group II.

3. Inventions I, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group I is drawn to composition, which has an amino acid, which is distinct and separate from group III that has an imaging agent. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group I would not anticipate or render obvious group III.

4. Inventions I, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group I is drawn to composition, which has an amino acid, which is distinct and separate from group IV that has a targeting moiety. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group I would not anticipate or render obvious group IV.

5. Inventions II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group II is drawn to composition, which has therapeutic agent, which is distinct and separate from group III that has an imaging agent. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group II would not anticipate or render obvious group III.

6. Inventions II, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group II is drawn to composition, which has therapeutic agent, which is distinct and separate from group IV that has a targeting moiety. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group II would not anticipate or render obvious group IV.

7. Inventions III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group III is drawn to composition, which has an imaging agent, which is distinct and separate from group IV that has a targeting moiety. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group III would not anticipate or render obvious group IV.

8. Inventions (I-IV) and (V-VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products. Groups I-IV are monomers where as groups V-VIII are polymers. Monomer and polymers have different structures and different modes of operation. Art anticipating or rendering obvious a monomer would not anticipate or render obvious a polymer.

9. Inventions (V-VIII) and (IX-XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products. Groups V-VIIII are polymers where as groups IX-XIII are drawn to polymers **and additional polymers added to** polymers. These two sets of groups have different structures and different modes of operation. Art anticipating or rendering obvious a polymer would not anticipate or render obvious a polymer and having another polymer.

10. Inventions (XIII-XVI) and (I-IV) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the biocompatible polymer formed by polymerization of monomers which has cyano acrylate can also be used for making a biocompatible monomer where in the monomer is methyl methacrylate. The process is drawn to polymerization of monomers only. Therefore this process is not only be used for the monomer claimed but also for any monomer.

11. Inventions (XVII-XX) and (XI-XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the first set polymerization is done *in vitro* where as the second set polymerization ism done *in vivo*. Both the sets of groups have different modes of operation and different effects.

12. Inventions XV and XVI or XVII or XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group XV delivers the agent which is an amino acid which is distinct and separate from other three groups which has either a therapeutic agent or an imaging agent or targeting moiety. All the groups are drawn to separate and distinct inventions.

13. It s a search burden to examine all the groups since there is no common structure core present. Note that the simplest structure shown in claim I has many structures depending on the

nature R' which is an organic residue. Not all the organic residues have common structure or in other words there is no special technical feature common to all the monomers. All the groups are drawn to distinct and separate inventions.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

15. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XXXII, restriction for examination purposes as indicated is proper.

If applicants elect any group, they are further required to elect species form

Amino acid

Imaging agent

Therapeutic agent

Targeting moiety

16. Due to complicated restriction requirement, telephone call was not made to applicants.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JYOTHSNA A VENKAT Ph. D
Primary Examiner
Art Unit 1615

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